DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 9 is drawn to functional descriptive material recorded on a computer readable medium. Normally, the claim would be statutory. However, the specification, at paragraph [0020] defines the claimed computer readable medium as encompassing statutory media such as a "compact disc, DVD, and magnetic media", but does not specifically define a computer-readable medium as only the given examples. In fact, paragraph [0020] states that the software application may be stored "as a network downloadable software package". Therefore, according to 1351 OG 212, dated 2/23/2010, computer readable medium will be reasonably interpreted to cover both non-transitory tangible media and transitory propagating signals per se in view of the ordinary and customary meaning of computer readable media. Furthermore, examiner notes that the cited interpretation is valid even if the specification is silent in regards to computer readable media and other such variations.

"A transitory, propagating signal ... is not a "process, machine, manufacture, or composition of matter." Those four categories define the explicit scope and reach of subject matter patentable under 35 U.S.C. § 101; thus, such a signal

cannot be patentable subject matter." (*In re Petrus A.C.M. Nuijten;* Fed Cir, 2006-1371, 9/20/2007).

Because the full scope of the claim as properly read in light of the disclosure encompasses non-statutory subject matter, the claim as a whole is non-statutory. The examiner suggests amending the claim to ***include*** the disclosed tangible computer readable media, while at the same time ***excluding*** the intangible media such as signals, carrier waves. Any amendment to the claim should be commensurate with its corresponding disclosure.

Examiner suggests, as seen within 1351 OG 212 dated 2/23/2010, applicant include the limitation, "non-transitory", within the cited claims to overcome the rejection and to avoid any issues of new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 5, and 9 include limitations pertaining to "locating at least one starting point within the at least one geometric shape", but this starting point is not claimed to be used for anything. What is it the start of?

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap

between the elements. See MPEP § 2172.01. Claims 1, 5, and 9 include limitations pertaining to "locating at least one starting point within the at least one geometric shape", but this starting point is not claimed to be used for anything. What is it the start of? Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The reasons are as stated above. Claims 1-9 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The reasons are as stated above. The depending claims do not remedy these deficiencies.

Claim 8 recites the limitation "the set of parameters". There is insufficient antecedent basis for this limitation in the claim.

35 USC § 103, sixth paragraph

Claims 5-8 are not presumed to invoke 35 U.S.C. 112, sixth paragraph (means-plus-function language), since the phrase "means for " is modified by sufficient structure, material, or acts for achieving the specified function (See MPEP 2181).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 rejected under 35 U.S.C. 103(a) as being unpatentable over USPGPubN 20020172406 (Rouet), USPN 6385332 (Zahalka), USPN 6701174 (Krause), and Xia-Limin, Gu-Shiwen, Shen-Xinquan, Fei-Yaoping, "3D surface reconstruction using fuzzy deformable models", ICSP 2000. 2000 5th International Conference on Signal Processing Proceedings. 16th World Computer Congress 2000, 2000, vol.2, p. 886-9 vol.2, 9 refs, pp. 3 vol. (Limin).

As per claim 5, Rouet teaches an ultrasound imaging system configured and disposed for defining internal structural borders in a medical ultrasonic image (208) comprising **(limitations only present within the preamble are not given patentable weight)**:

a display screen (204) for displaying signals in an operator-viewable format **(Rouet: para 67: "provide image data to display"; para 38; Figs. 1-5)**;

means for enabling an operator to indicate a region of interest (RoI) by placing at least one geometric shape in a proximal relationship to the RoI **(Rouet: para 1: "medical imaging apparatus... segmentation of objects that are body organs in order to study or detect organ pathologies"; para 18: "segmenting image permits detecting abnormalities or diseases of the organ"; para 6: "mesh model mapped onto said object surface"; para 22: "segmentation operation consists in mapping the three dimensional**

Simplex Mesh Model M0 of FIG. 1B onto the three dimensional object of interest C of FIG. 1A"; para 26: "segmentation operation consists in deforming the original spherical shape M0 of the Simplex Mesh Model in order to map it onto the object of interest C, that is to make its surface as close as possible to the surface of the object of interest C"); and

a processor (201) comprising **(Rouet: Fig. 6)**:

means for locating at least one starting point within the at least one shape **(Rouet: para 18: "segmenting image permits detecting abnormalities or diseases of the organ": Note that the abnormality would be comprised of at least one point in the image, which would be a starting point considering that there would be other points)**; and

means for detecting a tissue border and/or **(only one required)** structure within a portion of the image (208) bordered by the at least one shape by using one or more shapes having generally the shape of a bodily tissue or structure **(Rouet: para 1: "medical imaging apparatus... segmentation of objects that are body organs in order to study or detect organ pathologies"; para 18: "segmenting image permits detecting abnormalities or diseases of the organ")**.

Rouet does not teach an ultrasound transducer probe (206) configured for producing ultrasound signals, directing the ultrasound signals towards a target to be imaged, and detecting the ultrasound signals reflected from the target;

ultrasound; selected from a set of predetermined shapes; and a fuzzy border region.

Zahalka teaches an ultrasound transducer probe (206) configured for producing ultrasound signals, directing the ultrasound signals towards a target to be imaged, and detecting the ultrasound signals reflected from the target **(Zahalka: col 9, lines 34-54; col 10, lines 1-12)**;
a display screen (204) for displaying the reflected ultrasound signals in an operator-viewable format **(Zahalka: abstract: "ultrasound segmentation method comprising… geometrically deformable model"; col 2, lines 23-41; Fig. 6a, 7, 9, 11, 12; col 9, lines 33-54: "3-D volume which was viewed")**;
means for locating at least one starting point within the at least one shape **(Zahalka: abstract: "input of single seed point by the user"; col 2, lines 23-41)**.

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to implement the teachings of Zahalka into Rouet since Rouet suggests applying a deformable model to conform to a region of interest in a medical image in general and Zahalka suggests the beneficial use of applying a deformable model to conform to a region of interest in a medical image wherein the imaging modality used is ultrasound because of "its non-invasive nature" (col 1, lines 10-15), "the flexibility of ultrasound" col 1, lines 25-30, and "ultrasound is becoming increasingly popular" (col 1, lines 10-15) in the analogous art of

medical image analysis. Furthermore, one of ordinary skill in the art at the time the invention was made could have combined the elements as claimed by known methods and, in combination, each component functions the same as it does separately. One of ordinary skill in the art at the time the invention was made would have recognized that the results of the combination would be predictable.

Krause teaches using one or more shapes selected from a set of predetermined shapes, each having generally the shape of a bodily tissue or structure **(Krause: col 12, line 4-20: "access the 3D template geometry database 52 to select a 3D template bone model" col 12, lines 20-41: "selected template bone"; col 10, lines 1-20: "Module A 42 starts with a predefined three-dimensional template bone shape, whose shape is clinically normal and is scaled to an average size")**

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to implement the teachings of Krause into Rouet since Rouet suggests applying a deformable model to conform to a region of interest in a medical image in general and Krause suggests the beneficial use of applying a deformable model to conform to a region of interest in a medical image wherein a model is selected as to from among a plurality of models as to "start[] with a predefined three-dimensional template bone shape, whose shape is clinically normal and is scaled to an average size" (col 10, lines 1-2) and since "the 3D template geometry database 52 may contain 3D template bone models that

closely resemble actual, real-life patients' bones" (col 12, lines 35-41) in the analogous art of medical image analysis. Furthermore, one of ordinary skill in the art at the time the invention was made could have combined the elements as claimed by known methods and, in combination, each component functions the same as it does separately. One of ordinary skill in the art at the time the invention was made would have recognized that the results of the combination would be predictable.

Limin teaches a fuzzy border region **(Limin: abstract; abstract; pages 887-888: particularly section 3)**.

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to implement the teachings of Limin into Rouet since Rouet suggests applying a deformable model to conform to a region of interest in a medical image in general and Limin suggests the beneficial use of applying a deformable model to conform to a region of interest in a medical image wherein a fuzzy border region is used as to "make the result much less sensitive to the initial conditions and noise, fuzzy extemal forces that drive the model towards surface of object" (abstract) in the analogous art of medical image analysis. Furthermore, one of ordinary skill in the art at the time the invention was made could have combined the elements as claimed by known methods and, in combination, each component functions the same as it does separately. One of

ordinary skill in the art at the time the invention was made would have recognized that the results of the combination would be predictable.

As per claim 6, Rouet in view of Zahalka, Krause, and Limin teaches the system of claim 5, wherein the display screen (204) displays the image (208) with a plurality of delineations, the delineations identifying the tissue border and/or **(only one required)** structure on the display screen **(Rouet: Figs. para 67: "provide image data to display"; para 38; 1-5)**. Rouet does not teach ultrasound.

Zahalka teaches the display screen (204) displays the ultrasound image (208) with a plurality of delineations, the delineations identifying the tissue border and/or **(only one required)** structure on the display screen **(Zahalka: See arguments made for rejecting claim 1 above; Fig. 6a, 7, 9, 11, 12; col 9, lines 33-54: "3-D volume which was viewed")**.

The rationale made in rejecting claim 1 is analogous to that for rejecting claim 6.

As per claim 7, Rouet in view of Zahalka, Krause, and Limin teaches the system of claim 5, further comprising means for adjusting at least one **(only one required)** parameter from a set of parameters of the at least one selected

geometric shape to approximate the shape of the feature **(Rouet: See arguments made for rejecting claim 1 above)**.

As per claim 8, Rouet in view of Zahalka, Krause, and Limin teaches the system of claim 6, wherein the set of parameters includes size, position and orientation **(Rouet: See arguments made for rejecting claim 1 above)**.

Arguments made in rejecting claims 5-8 are analogous to arguments for rejecting claims 1-4 and 9. Note that limitations only present within the preamble are not given patentable weight, but Rouet teaches computer readable medium **(Rouet: para 67; Fig. 6)**.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Atiba Fitzpatrick whose telephone number is (571) 270-5255. The examiner can normally be reached on M-F 10:00am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Samir Ahmed can be reached on (571)272-7413. The fax phone number for Atiba Fitzpatrick is (571) 270-6255.

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